

N02C4

Phase III Double-Blind, Placebo-Controlled Randomized Comparison of Creatine for Cancer-Associated Weight Loss

ClinicalTrial.gov Identifier: NCT00081250

Study Background

Trial Description

RATIONALE: It is not yet known whether the supplement creatine is effective in increasing weight and improving appetite and quality of life in patients who have cancer. **PURPOSE:** This randomized phase III trial is studying how well creatine works in increasing weight and improving appetite and quality of life in patients with weight loss caused by cancer.

Arms:

Arm I: (Experimental): Patients receive oral creatine daily.

Arm II: (Placebo Comparator): Patients receive oral placebo daily.

Objectives:

- **OBJECTIVES:**
 - Compare weight-gain effects of creatine vs placebo in patients with cancer-associated weight loss and/or anorexia.
 - Determine the effect of these regimens on quality of life in these patients.
 - Compare the toxic effects of these regimens in these patients.
 - Compare survival rates of patients treated with these regimens.
- **OUTLINE:** This is a randomized, double-blind, placebo-controlled study. Patients are stratified according to primary cancer type (lung vs gastrointestinal vs other), weight loss severity (< 10 lbs vs ≥ 10 lbs), age (< 50 years vs ≥ 50 years), planned concurrent chemotherapy (yes vs no), gender, and prognosis. Patients are randomized to 1 of 2 treatment arms.
 - Arm I: Patients receive oral creatine daily.
 - Arm II: Patients receive oral placebo daily. In both arms, treatment continues in the absence of unacceptable toxicity as long as treatment is considered beneficial.
- Patients are followed every 6 months for up to 5 years.
- **PROJECTED ACCRUAL:** A total of 300 patients will be accrued for this study.

Study Milestones:

Start date: December 2004

Primary Completion Date: December 2007

Publication Information:

Analysis Type: Primary

Pubmed ID: 28475678

Citation: Ann Oncol. 2017 Aug 1;28(8):1957-1963. doi: 10.1093/annonc/mdx232.

Associated Datasets: NCT00081250-D1-Dataset.csv (qol), NCT00081250-D2-Dataset.csv (demo)

Dataset Information:

Dataset Name: NCT00081250-D1-Dataset.csv (qol)

Description: Dataset NCT00081250-D1-Dataset.csv (qol) is one of 2 datasets associated with PubMed ID 28475678. This dataset contains information that will allow you to reproduce the primary analysis as well as other quality of life analyses.

NB: To evaluate one-month QOL response, let CYCLE = 1 and WEEK = 4. Some minor discrepancies exist in Table 2 and 3 due to updates in data cleaning that do not alter any QOL outcomes.

NCT00081250-D1-Dataset.csv (qol) Data Dictionary:

- “Missing” corresponds to missing or unavailable data.

LABEL	NAME	elements	comments
Cycle	CYCLE		Cycle of treatment.
Reference ID	PATREF		Subject ID.
I have a good appetite	FACT01	Not At All, Missing, Quite A Bit, Some What, A Little Bit, Very Much	FAACT Questionnaire Question 1
The amount I eat is sufficient to meet my needs	FACT02	A Little Bit, Some What, Missing, Very Much, Quite A Bit, Not At All	FAACT Questionnaire Question 2
I am worried about my weight	FACT03	A Little Bit, Quite A Bit, Missing, Not At All, Some What, Very Much	FAACT Questionnaire Question 3
I have diarrhea	FACT04	Quite A Bit, Very Much, Missing, Some What,	FAACT Questionnaire Question 4

		A Little Bit, Not At All	
Most food tastes unpleasant to me	FACT05	Some What, A Little Bit, Missing, Very Much, Not At All, Quite A Bit	FAACT Questionnaire Question 5
I am concerned about how I look	FACT06	Very Much, Some What, Missing, Not At All, Quite A Bit, A Little Bit	FAACT Questionnaire Question 6
I enjoy eating breakfast or my first meal of the day	FACT07	Not At All, A Little Bit, Missing, Quite A Bit, Very Much, Some What	FAACT Questionnaire Question 7
I can swallow naturally and easily	FACT08	Quite A Bit, Very Much, Missing, Some What, A Little Bit, Not At All	FAACT Questionnaire Question 8
My mouth is dry	FACT09	Quite A Bit, Some What, Missing, Very Much, A Little Bit, Not At All	FAACT Questionnaire Question 9
My interest in food drops as soon as I try to eat	FACT10	Quite A Bit, Some What, Missing, Very Much, Not At All, A Little Bit	FAACT Questionnaire Question 10
I have difficulty eating rich or	FACT11	Some What,	FAACT

"heavy" foods		Very Much, Missing, A Little Bit, Quite A Bit, Not At All	Questionnaire Question 11
I enjoy eating my evening meal	FACT12	A Little Bit, Some What, Missing, Very Much, Quite A Bit, Not At All	FAACT Questionnaire Question 12
My family or friends are pressuring me to eat	FACT13	A Little Bit, Very Much, Missing, Not At All, Some What, Quite A Bit	FAACT Questionnaire Question 13
I have been vomiting	FACT14	Quite A Bit, Very Much, Missing, Some What, A Little Bit, Not At All	FAACT Questionnaire Question 14
When I eat, I seem to get full quickly	FACT15	Some What, A Little Bit, Missing, Very Much, Quite A Bit, Not At All	FAACT Questionnaire Question 15
I have pain in my stomach area	FACT16	Some What, Very Much, Missing, Quite A Bit, A Little Bit, Not At All	FAACT Questionnaire Question 16
I enjoy sweet foods	FACT17	A Little Bit, Very Much, Missing, Not At All,	FAACT Questionnaire Question 17

		Quite A Bit, Some What	
My general health is improving	FACT18	A Little Bit, Some What, Missing, Quite A Bit, Not At All, Very Much	FAACT Questionnaire Question 18
Do you do light household work?	FI1	Mostly, Sometimes, Missing, Never, Always	Frailty Index Questionnaire Question 1
Do you do heavy household work?	FI2	Sometimes, Never, Missing, Mostly, Always	Frailty Index Questionnaire Question 2
For how many people do you keep house?	FI3		Frailty Index Questionnaire Question 3
How many rooms do you keep clean?	FI4	1-6 Rooms, Missing, Never Do Housekeeping, 10 or More Rooms, 7-9 Rooms	Frailty Index Questionnaire Question 4
How many floors do you keep clean?	FI5		Frailty Index Questionnaire Question 5
Do you prepare warm meals yourself?	FI6	Always, Never, Missing, Sometimes, Mostly	Frailty Index Questionnaire Question 6
How many flights of stairs do you walk up per day?	FI7	Never Walk Stairs, Missing, 1-5 Flights,	Frailty Index Questionnaire Question 7

		6-10 Flights, >10 Flights	
If you go somewhere in your hometown, what kind of transportation do you use?	FI8	Car, Missing, Public Transportation, Never Go Out, Walking	Frailty Index Questionnaire Question 8
How often do you go out shopping?	FI9	Once a Week, Missing, Never, 2-4 Times a Week, Every Day	Frailty Index Questionnaire Question 9
If you go shopping, what kind of transportation do you use?	FI10	Car, Missing, Public Transportation, Walking, Never Go Out	Frailty Index Questionnaire Question 10
Do you play a sport?	FI11	No, Missing, Yes	Frailty Index Questionnaire Question 11
Do you have other interests that require physical activity?	FI12	No, Missing, Yes	Frailty Index Questionnaire Question 12
Do you work outside your home?	FI13	No, Missing, Yes	Frailty Index Questionnaire Question 13
Your overall Quality of Life?	LASA01		LASA Questionnaire Question 1
Your overall mental (intellectual) well-being?	LASA02		LASA Questionnaire Question 2
Your overall physical well-being?	LASA03		LASA Questionnaire Question 3
Your overall emotional well-being?	LASA04		LASA Questionnaire

			Question 4
Your level of social activity?	LASA05		LASA Questionnaire Question 5
Do you have persistent swelling of your legs or abdomen?	Q01	Yes, No, Missing	Anorexia Questionnaire Question 1
How would you compare your appetite now to what it was before your present illness?	Q02	Moderately Reduced, Missing, The Same, Increased, Markedly Reduced, Slightly Reduced	Anorexia Questionnaire Question 2
What is your current food intake in comparison to before your present illness?	Q03	Moderately Reduced, Missing, Increased, Markedly Reduced, The Same, Slightly Reduced	Anorexia Questionnaire Question 3
How would you rate/describe your appetite?	Q04	Poor, Missing, Very Good, Good, Fair, Very Poor	Anorexia Questionnaire Question 4
How do you presently feel about your weight status?	Q05	Stabilize or Increase Weight, Missing, Lose Weight, Not a Problem, Other	Anorexia Questionnaire Question 5
How much nausea have you had on an average over the previous week?	Q06	Moderate, None, Missing, Mild, severe	Anorexia Questionnaire Question 6

How many times have you vomited over the past week?	Q07	1-3 Times, 0 Times, Missing, 4-10 Times, >10 Times	Anorexia Questionnaire Question 7
How is your appetite now in comparison to before you started the study medications?	Q08	Missing, The Same, Increased Moderately, Increased Slightly, Reduced, Increased Considerably, Increased Very Much	Anorexia Questionnaire Question 8
What effect, if any, do you feel the study medications have had on your food intake?	Q09	Missing, Eat Slightly More, Eat Same Amount, Eat Less, Eat Considerably More, Eat Moderately More, Eat Very Much More	Anorexia Questionnaire Question 9
Do the study medications make food taste better?	Q10	Missing, No, Do Not Know, Yes	Anorexia Questionnaire Question 10
Do the study medications allow you to eat more at one time by preventing you from getting full soon after you start eating?	Q11	Missing, Do Not Know, Yes, No	Anorexia Questionnaire Question 11
Do you feel the study medications are:	Q13	Missing, Helping, Neither, Hindering	Anorexia Questionnaire Question 13
Do you feel the study medications	Q14	No,	Anorexia

are helping or hindering you, in what way?		Yes	Questionnaire Question 14
Impotence	Q12A	No, Yes	Anorexia Questionnaire Question 12A
Irregular menstrual periods	Q12B	No, Yes	Anorexia Questionnaire Question 12B
Nausea	Q12C	No, Yes	Anorexia Questionnaire Question 12C
Vomiting	Q12D	No, Yes	Anorexia Questionnaire Question 12D
Fluid retention	Q12E	No, Yes	Anorexia Questionnaire Question 12E
Muddled thinking	Q12F	No, Yes	Anorexia Questionnaire Question 12F
Drowsiness	Q12G	No, Yes	Anorexia Questionnaire Question 12G
Loss of coordination	Q12H	No, Yes	Anorexia Questionnaire Question 12H
Inappropriate behavior	Q12I	No, Yes	Anorexia Questionnaire Question 12I
Week of cycle	WEEK	1, NA = Not Provided, 2, 3, 4	Week of Cycle
Weight week 1 (lbs)	WEIGHT1		Weight
Fist Grip (kgs)	FISTGRPK		Fist grip strength in kilograms.
Value of resistance (Ohms, Ω)	RESISTANCE		Impedance test at 5 kHz.
Value of reactance (Ohms, Ω)	REACTANCE		Impedance test at

			200 kHz.
Arm	ARM	Placebo, Creatine	Treatment arm.